K083914

MAR 13 2009

510(k) Summary

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR Part 807, Section 807.92(c).

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Date Prepared: December 30, 2008

Device Information

Trade Name: AMPHIRION DEEP 0.014"OTW PTA Balloon Dilatation Catheter

Common Name: Percutaneous Transluminal Angioplasty Catheter

Regulation Name: Percutaneous Catheter

Predicate Devices

- Invatec AMPHIRION DEEP 0.014" OTW PTA Balloon Dilatation Catheters (K042624, K050073 & K052791)
- Clearstream Technologies SLEEK PTA Catheter (K072947)

Device Description

The AMPHIRION DEEP 0.014" OTW PTA Balloon Dilatation Catheter is an over-the-wire percutaneous transluminal angioplasty (PTA) catheter consisting of a proximal hub, coaxial dual lumen shaft, and a distal dilatation balloon. Hydrophilic coating covers the distal 240 mm of the catheter and radiopaque markers indicate the proximal and distal dilating surface of the balloon and facilitate placement across the stenosis. The AMPHIRION DEEP 0.014" OTW PTA Balloon Dilatation Catheter is compatible with

4 F introducer catheters and 0.014" diameter guidewires. The catheter is provided with useable catheter lengths of 120 cm and 150 cm.

Indication for Use

The AMPHIRION DEEP 0.014" OTW PTA Balloon Dilatation Catheters, with 150 mm and 210 mm balloon lengths, are intended to dilate stenoses in the femoral, popliteal, and infra-popliteal arteries.

Technological Characteristics

The AMPHIRION DEEP 0.014" OTW PTA Balloon Dilatation Catheter has the same or similiar design, materials and fundamental technology as the previously cleared AMPHIRION DEEP 0.014" OTW PTA Balloon Dilatation Catheters, and balloon lengths similar to the predicate Clearstream Technologies SLEEK PTA Catheter.

Performance Data

Bench testing of the AMPHIRION DEEP 0.014" OTW PTA Balloon Dilatation Catheter demonstrated that the device could meet the bench test acceptance criteria, and was comparable to the predicate devices. Biocompatibility testing was previously performed in accordance with ISO 10993-Part 1.

Conclusion

Based on similar intended use, technological characteristics, and performance characteristics, the AMPHIRION DEEP 0.014" OTW PTA Balloon Dilatation Catheter is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 13 2009

Invatec, Inc.
c/o Mr. Steve Camp
Vice President, Clinical and Regulatory Affairs
3101 Emrick Boulevard, Suite 113
Bethlehem, PA 18020

Re: K083919
Trade/Device Name: AMPHIRON DEEP 0.014" PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: December 30, 2008
Received: December 31, 2008

Dear Mr. Camp:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K083919

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Cardiovascular Devices

510(K) Number K083919